GOVERNMENT NOTICE DEPARTMENT OF CO-OPERATIVE GOVERNANCE

No. R. 2021

DISASTER MANAGEMENT ACT, 2002 DRAFT AMENDMENTS TO REGULATIONS ISSUED IN TERMS OF SECTION 27(2) OF THE DISASTER MANAGEMENT ACT, 2002

I, Dr Nkosazana Dlamini Zuma, Minister of Cooperative Governance and Traditional Affairs, designated under section 3 of the Disaster Management Act, 2002 (Act No. 57 of 2002), having declared a national state of disaster, published in Government *Gazette* No. 43096 on 15 March 2020, and extended by Government Notices Nos. 646 of 5 June 2020, 765 of 13 July 2020, 889 of 15 August 2020, 995 of 14 September 2020, 1090 of 14 October 2020,1225 of 14 November 2020 and 1341 of 11 December 2020, R. 15 of 13 January 2021 and R. 86 of 11 February 2021, hereby in terms of section 27(2) of the Disaster Management Act, 2002, after consultation with the relevant Cabinet members, hereby publish the draft Amendments to the Regulations issued in terms of section 27(2) of the Disaster Management Act as set out in the Schedule for public comment.

Written comments on the draft amendment to the Financial Sector Regulations should be submitted to NFCcomments@health.gov.za by close of business on 19 April 2021.

DR NKOSAZANA DLAMINI ZUMA, MP MINISTER OF COOPERATIVE GOVERNANCE AND TRADITIONAL AFFAIRS DATE:

SCHEDULE

Definitions

1. In these Regulations, "the Regulations" means the regulations published by Government Notice No. R. 480 of 29 April 2020 as amended by Government Notices Nos. R. 608 of 28 May 2020, R. 714 of 25 June 2020, R.763 of 12 July 2020, R 846 of 31 July 2020 R. 891 of 17 August 2020, 999 of 18 September 2020, 1011 of 20 September 2020, 1053 of 1 October 2020, 1104 of 21 October 2020. 1199 of 11 November 2020, 1290 of 3 December 2020, 1346 of 15 December 2020, 1370 of 17 December 2020, 1421 of 24 December 2020, 1423 of 29 December 2020, 1435 of 29 December 2020, R. 11 of 11 January 2021, R. 69 of 1 February 2021, R. 92 of 13 February 2021, R. 93 of 13 February 2021 and R. 152 of 28 February 2021.

Amendment of Classification of Regulations

2. The Classification of the Regulations is hereby amended by the addition of the following Chapter after Chapter 7:

"CHAPTER 8

COVID-19 VACCINE INJURY NO-FAULT COMPENSATION SCHEME

- 88. Definitions
- 89. Establishment of CoVID-19 Vaccine Injury No-Fault Compensation Scheme
- 90. CoVID-19 Vaccine Injury Compensation Fund
- 91. Financial management and oversight of Scheme
- 92. Administration of Scheme
- 93. Eligibility for Scheme
- 94. Amounts and structure of compensation
- 95. Scheme claim and claim through court process
- 96. Duration of Scheme".

Addition of Chapter 8 to the Regulations

3. The following Chapter is hereby added to the Regulations after Chapter 7:

"CHAPTER 8 CoVID-19 VACCINE INJURY NO-FAULT COMPENSATION SCHEME Definitions

- **88.** For the purposes of this Chapter, unless the context otherwise indicates— **'Fund'** means the COVID-19 Vaccine Injury Compensation Fund established by regulation 90 of the Regulations;
- 'Public Finance Management Act' means the Public Finance Management Act, 1999 (Act No. 1 of 1999); and
- **'Scheme'** means the COVID-19 Vaccine Injury No-Fault Compensation Scheme established by regulation 89 of the Regulations.

Establishment of CoVID-19 Vaccine Injury No-Fault Compensation Scheme

- **89.** (1) A CoVID-19 Vaccine Injury No-Fault Compensation Scheme is hereby established in terms of section 27(2)(c), (m) and (n) of the Act, under the auspices of the National Department of Health.
- (2) The Scheme is an essential part of the CoVID-19 vaccination roll-out, which is the most critical component of the national plan and response to alleviate, contain and minimise the effects of the disaster, and ultimately to end the State of National Disaster.
- (3) The purpose of the Scheme is to provide expeditious and easy access to compensation for persons who suffer vaccine injury referred to in regulation 93(2) and (4)(b) as a consequence of a CoVID-19 vaccine contemplated in regulation 93(4)(c) being administered.

CoVID-19 Vaccine Injury Compensation Fund

- 90. (1) The CoVID-19 Vaccine Injury Compensation Fund is hereby established.
- (2) The Cabinet Member responsible for Health, in consultation with the Cabinet member responsible for Finance, must designate the account for the Fund and the institution that is responsible for the financial management of the Fund in directions issued in terms of regulation 4.
 - (3) The Fund consists of—

- (a) funds appropriated by an Act of Parliament to the vote of Health or from contingencies in terms of appropriation legislation or the Public Finance Management Act; and
- (b) funds accruing from any other source.

Financial management and oversight of Scheme

91. The Cabinet member responsible for Finance may issue directions in terms of regulation 4 after consultation with the Cabinet member responsible for Health, in respect of the requirements relating to the financial management and oversight of the Scheme and the Fund that are in accordance with the Public Finance Management Act.

Administration of Scheme

- **92.** (1) The National Department of Health is responsible for the administration of the Scheme.
- (2) The Cabinet member responsible for Health, in consultation with the Cabinet member responsible for Finance, must designate an institution appointed in terms of subregulation (3) to conduct the administration of the Scheme in directions issued in terms of regulation 4.
- (3) (a) The Director-General of the National Department of Health may appoint a service provider to perform the administration, or certain administrative functions, for the Scheme, that has the necessary expertise and capacity to perform the functions efficiently, effectively, competently and fairly.
- (b) The applicable procurement procedures in terms of the Public Finance Management Act, 1999 and any other legislation must be followed when appointing a service provider referred to in paragraph (a).
- (c) The service provider appointed in terms of subregulation (3) is accountable to the Director-General of the National Department of Health as the accounting officer of the Scheme.
- (d) The terms and conditions of employment of the employees of the service provider are determined in terms of their contracts of employment with the service provider.
- (e) Accounting by the service provider must be in accordance with directions issued by the Cabinet member responsible for Finance.
- (4) In order to ensure the effective and efficient administration of the Scheme in a manner that ensures fairness in the assessment and administration of claims, and respects the constitutional rights of claimants, the Cabinet member responsible for Health must issue directions in terms of regulation 4 in consultation with the Cabinet member responsible for Finance in respect of—
 - (a) the requirements relating to the administration of the Scheme;
 - (b) the policy in respect of the administration of the Scheme;
 - (c) the reporting of vaccine injuries;
 - (d) the claims system;
 - (e) the reporting of claims; and
 - (f) any other matter relevant for the effective, efficient and fair administration of the Scheme.
- (5) (a) The Cabinet member responsible for Health must appoint an adjudication panel and an appeal panel to deal with the adjudication of, and appeals in respect of, claims.
- (b) The adjudication and appeal panels must have suitably qualified medical and any other relevant experts, to assess claims under the Scheme.
- (c) The members of the panels, if they are not currently employed under an employment contract with the Department of Health, are appointed for the period, and on the terms and conditions, determined in writing by the Cabinet member responsible for Health.

- (6) (a) The Cabinet member responsible for Health, in consultation with the relevant Cabinet members, must appoint a Governance and Oversight Committee, headed by a retired Judge, and comprised of medical, actuarial, legal and any other relevant experts, that will be responsible for overseeing the policies, and reporting, of the Scheme and for advising the Cabinet member responsible for Health.
- (b) The retired Judge referred to in paragraph (a) must be appointed in terms of the Judges' Remuneration and Conditions of Employment Act, 2001 (Act No. 47 of 2001).
- (c) The other members of the Governance and Oversight Committee, if they are not currently employed under an employment contract with the Department of Health, are appointed for the period, and on the terms and conditions, determined in writing by the Cabinet member responsible for Health.
 - (7) The directions referred to in subregulation (4)—
 - (a) must provide for an appeal mechanism in respect of claims under the Scheme; and
 - (b) may not be inconsistent with the constitutional rights of claimants.

Eligibility for Scheme

- **93.** (1) Subject to this regulation, a person who has suffered a vaccine injury referred to in subregulations (2) and (4)(b) caused by the administration of a COVID-19 vaccine contemplated in subregulation (4)(c) that is registered or otherwise approved by the South African Health Products Regulatory Authority and procured and distributed by the National Government, at a facility within the Republic specified in terms of subregulation (4)(d), is eligible for compensation under the Scheme.
- (2) Vaccine injuries referred to in subregulation (4)(b) that are covered under the Scheme are severe injuries resulting in permanent or significant injury, serious harm to a person's health, other damage or death.
- (3) Vaccine injuries referred to in subregulations (2) and (4)(b) that are determined by a panel referred to in regulation 88(5) to be causally related to a vaccination of a COVID-19 vaccine contemplated in subregulation (4)(c) which has been procured by the National Government, are covered by the Scheme.
- (4) The Cabinet member responsible for Health, in consultation with the Cabinet member responsible for Finance, must issue directions in terms of regulation 4 specifying—
 - (a) persons eligible to make claims under the Scheme;
 - (b) the vaccine injuries covered;
 - (c) the specific vaccines to be covered;
 - (d) facilities in the Republic referred to in subregulation (1) where CoVID-19 vaccinations are officially administered;
 - (e) the timeline and duration of injury and the period of vaccinations that the Scheme will cover;
 - (f) the types of claims that may be made;
 - (g) requirements and procedures for instituting claims; and
 - (h) the period in respect of which claims may be instituted with the Scheme.

Amounts and structure of compensation

94. The Cabinet member responsible for Health, in consultation with the Cabinet member responsible for Finance, must issue directions in terms of regulation 4 specifying the amounts and structure of compensation that will be provided under the Scheme.

Scheme claim and claim through court process

95. (1) A person who claims to have suffered harm, loss or damage arising from a vaccine injury referred to in regulations 93(2) and (4)(b) in relation to a vaccine contemplated in regulation 93(4)(c), and who elects to institute a claim with the Scheme, may not institute a

claim through a court process against the National Government or any Provincial Government—

- (a) until the claim has been adjudicated by the relevant panel; and
- (b) unless the person is dissatisfied with the outcome of the adjudication or the amount awarded, and the person has lodged an appeal and the appeal has been determined by the relevant decision-maker.
- (2) If, after pursuing a claim with the Scheme, a person succeeds in claiming damages through a court process against the National Government or any Provincial Government for a vaccine injury referred to in regulation 93(2) and (4)(b) in relation to a vaccine contemplated in regulation 93(4)(c), the amount of damages awarded by the court must be reduced by the amount paid or due to the person from the Scheme.
- (3) A claim for damages through a court process arising from a vaccine injury referred to in regulation 93(2) and (4)(b) in relation to a vaccine contemplated in regulation 93(4)(c) and said to have been caused by the conduct of a vaccine manufacturer—
 - (a) may not be brought against the vaccine manufacturer; and
 - (b) may only be brought against the National Government, to the extent that the National Government granted an indemnity to the manufacturer of the vaccine under the vaccine procurement agreement in terms of which the vaccine dose that was provided to the person was obtained.
- (4) A claim for damages through a court process arising from a vaccine injury referred to in regulation 93(2) and (4)(b) in relation to a vaccine contemplated in regulation 93(4)(c) and said to have been caused by the conduct of an organ of state, service provider, health establishment, facility specified in regulation 93(4)(d) or person who was performing authorised functions relating to the distribution or administration of the vaccine in terms of the National Government's vaccination programme—
 - (a) may not be brought against the service provider, health establishment or person whose conduct is said to have caused the damages claimed; and
 - (b) may only be brought against the National Government or the relevant Provincial Government, both of which are vicariously liable for the conduct of the organ of state, service provider, health establishment, facility specified in regulation 93(4)(d), or person who was performing authorised functions relating to the distribution or administration of the vaccine in terms of the National Government's vaccination programme.
- (5) Claims referred to in subregulations (3) and (4) are subject to the provisions of subregulations (1) and (2).

Duration of Scheme

- **96. (**1) The provisions of this Chapter, the directions issued in terms hereof and the existence of the Scheme—
 - (a) will continue to operate and be of force and effect until the Cabinet member responsible for Cooperative Governance is, after consultation with the relevant members of the Cabinet, satisfied that the implementation of all measures necessary to prevent an escalation of the disaster, or to alleviate, contain and minimise the effect of the disaster have been concluded; and
 - (b) will continue to operate and be of force and effect until—
 - (i) they are repealed; or
 - (ii) a notice is published by the Minister of Health, in consultation with the Minister of Finance, in the *Government Gazette* terminating the Scheme.
- (2) The regulations and directions referred to in subregulation (1)(b)(i) may not be repealed, or the *notice* contemplated in subregulation (1)(b)(i) may not be issued until—
 - (a) the period for the lodgment of claims with the Scheme has expired; and
 - (b) all claims lodged with the Fund have been finalised.".